

MEETING AGENDA
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
September 20–21, 2018

One White Flint North Building (Commission Hearing Room), Rockville, Maryland

NOTE: Sessions of the meeting may be closed pursuant to 5 U.S.C. 552(b) to discuss organizational and personnel matters that relate solely to internal personnel rules and practices of the ACMUI; information the release of which would constitute a clearly unwarranted invasion of personal privacy; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and disclosure of information which would risk circumvention of an agency regulation or statute.

Thursday, September 20, 2018
CLOSED SESSION

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| 7:30 – 10:30 | <ul style="list-style-type: none">• Badging and Enrollment• INFOSEC Training• Ethics Training• Allegations Training | PERSEC, NRC
R. Norman, NRC
J. Suttenger & J. Ezell, NRC
D. Willis, NRC |
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10:30 – 11:00 **BREAK**

OPEN SESSION

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| 11:00 – 11:45 | <ul style="list-style-type: none">• Opening Remarks
Mr. Bollock will formally open the meeting and Ms. Attack will provide opening comments.• Old Business
Ms. Dimmick will review past ACMUI recommendations and provide NRC responses.• Open Forum
The ACMUI will identify medical topics of interest for further discussion. | D. Bollock & S. Attack, NRC

L. Dimmick, NRC

ACMUI |
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11:45 – 12:45 **LUNCH**

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| 12:45 – 2:30 | <ul style="list-style-type: none">• Medical Events Subcommittee Report
Dr. Ennis will present the subcommittee's analysis of medical events for fiscal year 2017.• Non-Medical Events
Mr. Sheetz will did non-medical events reported by medical use facilities and commercial pharmacies.• ABS Medical Event Case Study Program
Mr. Ouhib will discuss the American Brachytherapy Society's effort to reach out to the brachytherapy community for creative corrective actions regarding events that have taken place. | R. Ennis, ACMUI

M. Sheetz, ACMUI

Z. Ouhib, ACMUI |
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2:30 – 2:45 **BREAK**

- **T&E for All Modalities Subcommittee Update** **D. Metter, ACMUI**
Dr. Metter will provide an update on the actions of the training and experience for all modalities subcommittee and the planned path forward.
- **T&E Stakeholder Outreach Plan** **M. Ayoade, NRC**
Ms. Ayoade will present the staff's outreach plan for the continued evaluation of training and experience.
- **ACMUI-SNMMI Session at the 2018 SNMMI Annual Meeting** **C. Palestro, ACMUI**
Dr. Palestro will provide an overview of the topics discussed by ACMUI at the 2018 SNMMI meeting in Philadelphia, PA.
- **Nursing Mother Guidelines Subcommittee Report** **D. Metter, ACMUI**
Dr. Metter will discuss the subcommittee's final report on the nursing mother guidelines for exposure from diagnostic and therapeutic radiopharmaceuticals.
- **ACMUI Comments on the Draft Revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ Licensing Guidance** **J. Suh, ACMUI**
Dr. Suh will discuss the subcommittee's comments on the draft revision of the Leksell Gamma Knife® Perfexion™ and Leksell Gamma Knife® Icon™ licensing guidance.

Friday, September 21, 2018
OPEN SESSION

- **Special Presentation to Dr. Suh** **M. Dapas, NRC**
Mr. Dapas will make a special presentation to Dr. Suh.
- **Dr. Suh's Thoughts on Leaving ACMUI** **J. Suh, ACMUI**
Dr. Suh will share his thoughts on leaving the ACMUI.
- **Special Presentation to Dr. Alderson** **M. Dapas, NRC**
Mr. Dapas will make a presentation to Dr. Alderson.
- **Dr. Alderson's Thoughts on Leaving ACMUI** **P. Alderson, ACMUI**
Dr. Alderson will share his thoughts on leaving the ACMUI.
- **Y-90 Microspheres Brachytherapy Licensing Guidance** **K. Tapp, NRC**
Dr. Tapp will discuss the current status of the yttrium-90 working group's revised guidance and planned actions.

10:15 – 10:45 **BREAK**

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| 10:45 – 11:15 | <ul style="list-style-type: none"> Compounding of Sterile and Non-Sterile Radiopharmaceuticals
 Mr. Green will discuss the establishment of an Expert Panel by USP to develop USP Standards of sterile and non-sterile radiopharmaceutical preparation. | R. Green, ACMUI |
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11:15 – 12:00	<ul style="list-style-type: none"> • Medical Team Highlights Ms. Dimmick will recap the work of the Medical Radiation Safety Team for fiscal year 2018. • Open Forum The ACMUI will discuss medical topics of interest previous identified. 	<p>L. Dimmick, NRC</p> <p>ACMUI</p>
12:00 – 1:00	LUNCH	
1:00 – 3:00	<ul style="list-style-type: none"> • ACMUI, Subcommittees, NRC staff, NRC management: How the Team Works Under FACA Mr. Chazell and Mr. Bollock will discuss the roles and responsibilities of each under the Federal Advisory Committee Act (FACA). • ACMUI Subcommittees, Subcommittee Membership, and the ACMUI Chair Dr. Palestro will discuss the possible need for ACMUI bylaw changes and the need to update subcommittee membership, form new subcommittees and sunset other subcommittees. • Administrative Closing Ms. Dimmick will provide a meeting summary and propose dates for the spring 2019 meeting. 	<p>R. Chazell & D. Bollock, NRC</p> <p>C. Palestro, ACMUI</p> <p>L. Dimmick, NRC</p>
3:00	ADJOURN	